federal register

Friday
January 25, 1980

Part V

Department of Health, Education, and Welfare

Food and Drug Administration

Nutritional Quality of Foods; Addition of Nutrients

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 104

[Docket No. 79N-0377]

Nutritional Quality of Foods; Addition of Nutrients

AGENCY: Food and Drug Administration.

ACTION: Final policy statement.

SUMMARY: This statement establishes a Food and Drug Administration (FDA) policy concerning the nutrient fortification of foods and is expressed as a series of guidelines which manufacturers are urged to follow if they elect to add nutrients to a manufactured or processed food. This final policy statement is to promote the rational addition of nutrients to foods in order to preserve a balance of nutrients in the diet of American consumers. It is not intended to encourage widespread nutrient fortification of foods but rather to provide a consistent set of guidelines to be followed when foods are nutritionally improved by the addition of discrete nutrients (vitamins, minerals, or protein). This statement establishes FDA's policy with respect to labeling claims that may be used to describe specific fortification mechanisms. In addition, it states that FDA considers it inappropriate to make claims about the addition of nutrients to foods that have been fortified to make them nutritionally equivalent to the foods for which they substitute and resemble. This policy statement omits the proposed requirement for a label statement that the addition of nutrients is unnecessary and inappropriate if the food has been fortified in ways not described in the policy statement. FDA will continue to determine in specific situations whether labeling claims about nutrient additions may be false or misleading in the case of foods fortified in ways not provided for in these guidelines.

EFFECTIVE DATE: February 25, 1980.

FOR FURTHER INFORMATION CONTACT: John E. Vanderveen, Bureau of Foods (HFF-260), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-1064.

SUPPLEMENTARY INFORMATION: The analysis of evidence from food labeling hearings conducted in the summer and fall of 1978 indicates general public support for the principles expressed in this document. Policy changes with respect to labeling made in response to the hearings are not likely to affect the guidelines for the addition of nutrients to food set forth in this document. This document primarily provides guidelines for fortification and contains few labeling provisions. Nonetheless the issuance of these guidelines may provide additional background for those commenting on the food labeling plan proposal. In reviewing the comments on the food labeling plan, FDA will consider whether any changes are needed in these guidelines and will initiate the changes if warranted.

In the **Federal Register** of June 14, 1974 (39 FR 20900) FDA proposed to establish general principles governing the addition of nutrients to foods by amending Subpart A of Part 104 (21 CFR Part 104, formerly 21 CFR Part 100). That document described the history of developments that led to the proposal. The major reasons for initiating this proceeding are summarized below.

"Food fortification" or "enrichment" is defined as the addition of discrete nutrients such as vitamins, minerals, or protein to foods. Historically, the addition of nutrients to foods was first undertaken as a public health measure to prevent the development of deficiency diseases in large segments of the population, for example, the iodization of salt to prevent goiter and the addition of vitamin D to milk to prevent rickets. The addition of nutrients primarily for the purpose of restoring nutrients lost in processing, such as the enrichment of white flour and bread, has been a similar safeguard in preventing deficiencies and improving the nutritional quality of the national diet.

In the past, food intake was largely from conventional foods having an inherent nutritional quality dictated primarily through the forces of nature. In recent years the food supply has become more complex as an increasing volume of foods with new or processed ingredients and substitute foods have entered the marketplace. Because of these changes in the food supply and their effects on American eating habits, FDA has paid increasing attention to the need for maintaining the nutritional quality of the food supply.

FDA has established in recent years a number of regulations relating to the nutritional quality of foods. The regulations have included nutrition labeling under § 101.9 (21 CFR 101.9, formerly 21 CFR 1.17); special dietary foods under Part 105 (21 CFR Part 105, formerly 21 CFR Part 125); nutritional quality guidelines under Part 104 (21 CFR Part 104, formerly 21 CFR Part 100); and imitation food labeling under § 101.3 (21 CFR 101.3, formerly 21 CFR 1.8(e)).

Some of these regulatory initiatives were established in response to changes in food technology and dietary consumption patterns. They were necessary in order for FDA to cope with the dynamics of modern food technology and the development of new food products. At the same time, FDA sought by issuing these regulations to respond to recommendations generated by the 1969 White House Conference on Food, Nutrition, and Health; the Food and Nutrition Board of the National Academy of Sciences/National Research Council (NAS/NRC); and the Council on Foods and Nutrition of the American Medical Association.

One of the recommendations generated by the 1969 White House Conference on Foods, Nutrition, and health was that existing nutritional requirements in Federal regulations for foods be reviewed to take account of accumulated knowledge about nutritional needs and changing patterns of food consumption. In addition, there have been increasing consumer demands for improved nutrition information.

In the 1974 **Federal Register** proposal, FDA stated that during the development of regulations related to nutrition the need became apparent for a unifying set of principles or guidelines governing the addition of vitamins, minerals, and protein to food.

In the preamble to the proposal, FDA also emphasized that the proposed regulation was not intended to encourage the food industry to put vitamins, minerals, or protein into every food. Not every food is an appropriate carrier for additional nutrients, and unwarranted fortification of numerous foods could mislead consumers into believing such fortification is necessary or appropriate and could lead to public health problems.

FDA's policy continues to be that current nutrition surveys show that widespread fortification of the food supply is unnecessary. This document is not intended to encourage such a practice.

The fundamental premise underlying these guidelines is that food fortification should provide consumers with a reasonable benefit without contributing to nutritional imbalance in the diet and without misleading consumers into believing that the consumption of the fortified food per se will ensure a complete or nutritionally sound diet.

In the absence of a unifying set of principles or guidelines, random and arbitrary fortification of some foods is likely to occur. This may result in the overfortification of the food supply with some nutrients such as vitamin C, which

are inexpensive and technologically simple to add, and the underfortification with others such as some of the trace minerals. A balance of the essential nutrients is biologically necessary for proper nutrition; therefore, a reasonable balance of essential nutrients in the food supply is desirable. In addition, overfortification of the food supply by the random addition, and/or the addition of high levels, of some nutrients, such as vitamin D and the trace minerals, is undesirable because of the potential for toxicity.

This position has been further supported by comments received at the food labeling hearings conducted during the summer and fall of 1978. The analysis of comments from these hearings discloses a public belief that some, but not all, foods should be fortified. Particular support exists for fortification if the purpose is to replace nutrients lost in processing. Of those favoring fortification, some felt that the extent to which foods could be fortified should be closely regulated.

The 1974 proposal discussed the fact that some existing standards of identity permit or require the addition of vitamins, minerals, and/or protein to improve the nutritional quality of a product (for example, enriched flour) under 21 CFR 137.165 (formerly 21 CFR 15.10). The document concluded, however, that a separate standard of identity for each food to which a vitamin, mineral, and/or protein may properly be added is neither practical nor appropriate and that a single standard of identity listing all foods to which a vitamin, mineral, and/or protein may be added would be unnecessarily inflexible in light of developing knowledge about nutrition and changing food forms and consumption patterns.

In the past the addition of a vitamin or mineral to a food resulted in the food being classified as a "special dietary food." In the proposal for the nutrition labeling regulation (38 FR 2125; January 19, 1973), FDA concluded that a majority of fortified foods were intended for consumption by the general population and that with the development of nutrition labeling it was no longer necessary to regulate nutrient labeling of these general purpose foods as labeling for special dietary foods under section 403(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(j)).

As a result of the complexity and diversity of current regulations relating to the nutritional quality of foods, FDA considers it appropriate to combine in a single document those general nutrition principles and guidelines that serve as the basis for FDA's food fortification policy. FDA believes that there is a need for a clear statement of policy to serve as a guideline on food fortification.

Although, as a theoretical matter, most types of food can be fortified under the general principles expressed in this document, FDA emphasizes that, as a matter of policy, it does not consider it appropriate or reasonable to fortify certain classes of food such as fresh produce, fresh meat, poultry or fish products, sugars, or snack foods such as candies and carbonated beverages. In some cases, fortification of these foods is already restricted by a specific regulation that applies to that food. For example, the standard of identity for carbonated beverages (21 CFR 165.175) states that the addition of vitamins and minerals for nutritional purposes is not suitable for this food.

FDA sees no reason to add nutrients to fresh produce, meat, poultry, or fish products. The use of these foods is firmly established by customary dietary practice, and their role in a balanced diet is well understood by the public. FDA also believes it is inappropriate to fortify snack foods such as candies and carbonated beverages. These foods are not considered by the public as components of meals, and even if snack foods are used with meals, their nutritional contribution is, and is understood by the public to be, incidental. To date, neither the public nor the scientific community has considered snack foods to be appropriate carriers for added nutrients, given the general adequacy and diversity of the national food supply. Their fortification could readily mislead consumers to believe that substitution with fortified snack foods would ensure a nutritionally sound diet. Moreover, such fortification would disrupt public understanding about the nutritional value of individual foods and thereby promote confusion among consumers and make it more difficult for them to construct diets that are nutritionally neither excessive nor deficient. This policy is based on U.S. dietary practices and nutritional needs and may not be applicable in other countries.

Moreover, any fortification of these foods would raise other questions with respect to the labeling appropriate for them. The fortification of snack foods can be viewed, for example, as a basic change in the nature of the food. Consideration would be needed of the type of common or usual name that would adequately reflect the distinctive characteristics of the new food.

The following are the principal differences between the proposed regulation and the policy announced by this document:

a. The criteria for balancing nutrients to calories as a fortification mechanism have been changed so that the calorie base is reduced from 2,800 to 2,000 kilocalories. Two essential nutrients (potassium and manganese) not in the original list of nutrients have been included; and the addition of protein, vitamin D, or iodine has been made optional.

b. The definition for "restoration" has been changed so that partial restoration is no longer recommended. If the restoration mechanism is used, all nutrients originally present at more than 2 percent of the U.S. Recommended Daily Allowances (U.S. RDA) per serving, and which later are lost in storage and/or processing by an amount equal to at least 2 percent of the U.S. RDA per serving, should be restored to preprocessing levels.

c. Separate definitions for "enriched" and "fortified" have been deleted. The terms may be used interchangeably unless another regulation provides for use of a specific term, for example, 21 CFR 137.165 for enriched flour.

d. The proposed expansion of the use of the affirmative statement permitted by 21 CFR 104.5(b) (formerly 21 CFR 100.1(b)) for food complying with a nutritional quality guideline has been deleted along with labeling proscriptions not directly associated with a statement of policy.

e. This final policy statement deletes the proposed requirement in § 100.1(h) under which foods fortified in ways other than those in the proposal would have had to bear a label statement that the addition of the nutrients to this product has been determined by the U.S. Government to be unnecessary and inappropriate and does not increase the dietary value of the food. The final policy statement contains a new provision in § 104.20(h) that makes it clear that other labeling statements concerning food fortification may be made only if they are not false or misleading and are otherwise in accordance with the Federal Food, Drug, and Cosmetic Act and applicable regulations.

f. Section 104.20(a) has been added to provide an introductory statement of the purpose of the guidelines. Other editorial changes have also been made.

The reasons for these changes and modifications from the proposed course of action are individually discussed elsewhere in this document.

A total of 122 comments on the 1974 proposal were received from individuals, consumers and professional groups, trade associations, and industry and industry representatives. The comments generally favored the concept

of establishing rational guidelines for the addition of nutrients to foods. There were, however, several objections to the form and substance of the proposal and many more requests for clarification of specific provisions of the proposal. These comments and FDA's responses are discussed in the following paragraphs:

1. Several comments from industry objected to the length, complexity, and alleged unwieldiness of the proposal. One comment criticized the language of the proposal as vague and obscure and asked that the document be redrafted and published as a new proposal. A number of other comments reflected confusion and asked whether certain provisions of the proposal were applicable to all foods or only to the specific classes of food for which nutritional quality guidelines have been established. The U.S. Department of Agriculture asked that the conditions under which nutrients may be added to food be more clearly identified in the regulation to promote understanding and ease of implementation. Many comments opposed the proposal because of the requirements for label statements, particularly the requirement for a statement that the addition of nutrients in ways not provided for in the guidelines was "unnecessary and inappropriate."

It is acknowledged that the criteria to be used in determining whether nutrient addition would be appropriate were not clearly defined, and that all possible labeling was not dealt with in the proposal. Further, FDA has concluded that a substantive rule that would accommodate all eventualities involving food fortification and labeling of fortified foods is not feasible at this time.

The primary purpose of the regulation proposed in 1974 was to establish a general set of principles governing the addition of nutrients to foods to preserve a balance of nutrients in the diet and to prevent over- or underfortification of the food supply. The proposal also included a number of food labeling provisions. Thus the proposal was an attempt to cover, in a single document, both FDA's food fortification policy and the complex labeling issues related to fortified foods.

The proposed regulation and the comments received have been evaluated in relation to the FDA's existing nutrition regulation programs. After thorough review, FDA has concluded that the major objectives of the proposal can be achieved by recasting the final document as a statement of food fortification policy. Several labeling provisions have been deleted or revised. The final policy statement is a guideline that identifies the bases for fortification of foods that FDA considers reasonable. The appropriateness of the fortification of foods in ways not provided for in these guidelines and associated labeling problems will be considered as the need arises. FDA will continue to examine food labeling under the existing law and regulations and will take any necessary action concerning specific foods if the labeling is found false or misleading or otherwise in violation of the FD&C Act.

In reaching this conclusion, FDA has considered the large number of comments stating opposition to the restrictive nature of the labeling provisions of the proposal. These comments presented convincing arguments that all possible labeling and fortification circumstances cannot be addressed adequately in a single substantive rule at this time.

Much of the confusion and many of the objections with regard to the complexity of the 1974 proposal appear to have been related to its labeling provisions and their applicability to the various fortification principles. Most of these labeling provisions have been deleted from the final policy statement. In view of these changes and because this final policy statement is a guideline, it is not necessary to repropose it for additional comments. FDA guidelines "state procedures or standards of general applicability that are not legal requirements but that are acceptable to FDA for a subject matter which falls within the laws administered by the Commissioner." * * *" (See 21 CFR 10.90(b)(1).) Section 10.90(b) contains a general discussion of the legal status of a guideline.

FDA will continue to rely on the establishment of nutritional quality guidelines for particular classes of foods under 21 CFR Part 104 and on standards of identity for specific foods as the need arises. In addition, problems that arise concerning food labeling as it pertains to fortified foods can be considered independently; and appropriate actions, such as amendment of current food labeling regulations, can be taken when necessary.

2. A number of comments from industry objected to the labeling provisions of the proposal on the grounds that they exceed FDA's statutory authority and disregard procedural safeguards guaranteed by law. It was argued that sections 403(a) and 701(a) of the FD&C Act can only define "false or misleading" labeling and cannot be used to regulate truthful labeling claims. Other comments argued that the proposal was unlawful because it created a conclusive presumption that labeling that fails to conform to the regulations causes the food to be misbranded under the act without regard to whether, in any particular case, the food is actually misbranded. Other comments objected to the proposal on the grounds that as a substantive rule it was too restrictive and that it did not include all possible mechanisms by which foods may be appropriately fortified. Other comments stated that the proposal, in effect seeks to establish standards of quality for foods fortified with vitamins and minerals and that, accordingly, FDA is bound to follow the procedural requirements of sections 401 and 701(e) of the FD&C Act.

As stated earlier, FDA has concluded that the best way to achieve its objectives at this time is to issue a statement of policy regarding food fortification and to regulate misleading claims under the general statutory provisions and applicable regulations. Because FDA has decided to issue a statement of policy rather than a regulation, the merits of the above-described objections need not be determined. The issues raised concerning the legality of the proposal under the FD&C Act are now moot.

The following discussion of the provisions of the guidelines responds to specific comments on the 1974 proposal:

Addition of Nutrients as a Public Health Measure

3. A number of comments concerned proposed § 100.1(g)(1), which set forth certain criteria to be used whenever nutrients are added to foods for the purpose of reducing the prevalence of identified nutrient deficiency conditions. Several comments asked who determines whether the criteria set forth in proposed § 100.1(g)(1) (i), (ii), and (iii) have been met in any particular case. Other comments asked whether additional rulemaking would be needed before manufacturers could apply this principle. Still other comments suggested that proposed § 100.1(g)(1) be identified only as a statement of important criteria or indices against which all fortification policies can be evaluated.

The addition of specific nutrients to certain foods has served to correct deficiency conditions in large segments of the population. The addition of nutrients for the purpose of correcting identified dietary insufficiencies has been retained in the final policy statement because it remains an appropriate reason for adding nutrients to foods. In the past, FDA has endorsed this principle through the establishment of standards of identity for products

such as enriched flour, bread, and rice. Such public health measures may continue to be of importance in the prevention of nutrient deficiency diseases where sufficient information is available to identify a nutritional problem, to define affected population groups, and to designate suitable foods to act as vehicles for the added nutrients.

Identification of nutritional problems and implementation of measures to correct these problems require the combined efforts of many participants. Because FDA is responsible for the safety and nutritional adequacy of the food supply and the truthful packaging and labeling of food products, it is appropriate that FDA serve as a focal point for the identification of public health problems related to nutrition. In conjunction with other government agencies, research groups, the biomedical and nutrition communities, educational institutions, and informed consumer groups, FDA participates in the collection and exchange of information relating to nutritional problems.

Accordingly, the final policy statement provides for adding nutrients to foods to prevent identified nutrient deficiencies. The criteria found in proposed § 100.1(g)(1) (iv), (v), and (vi), because they are universally applicable to nutrient additions, have been transferred to new § 104.20(g).

Manufacturers may make labeling statements based on the criteria listed in this rule without awaiting further rulemaking by FDA. Before making a claim relating to fortification, a manufacturer should have the types of specific data identified in the guideline to document the appropriateness of the claim. If FDA believes that a claim for a particular food is false or misleading or otherwise in violation of the act, the agency will take appropriate enforcement action.

Nutrients Added in Accordance With Other Regulations To Raise the Nutritional Quality of a Food

4. The comments received on proposed § 100.1(g)(2), which dealt with nutrients added to raise the nutritional quality of the foods, were directed generally toward clarification of the intent and meaning of this paragraph.

One comment criticized this proposed principle as being too vague and theoretical to be used as a working guideline for industry. Other comments asked for clarification as to when it is necessary to raise the nutritional quality of a food and how to determine what is appropriate for a food. A city health department asked for clarification of the difference between proposed § 100.1 (g)(2) and (g)(4), which relates to restoration of nutrients to foods.

The principle proposed in § 100.1(g)(2) was intended to be a generalized principle that would permit the addition of nutrients to a food or class of foods when necessary to comply with a standard of identity, a nutritional quality guideline, a common or usual name regulation, or any other Federal regulation. In the absence of any applicable Federal regulation, § 100.1(g)(3) would have permitted nutrient addition on the basis of balancing nutrients to calories.

In the final policy statement, § 104.20(f) has been substituted for § 100.1(g)(2). Section 104.20(f) states that nutrients may be added to foods as permitted or required by applicable Federal regulations. Existing regulations prescribing the addition of nutrients to food are based upon the best available scientific data on food consumption patterns, nutritional needs and dietary habits of the general population and may encompass concepts of enrichment/fortification and restoration of nutrients. Nutrient addition based on balancing nutrients to calories, proposed in § 100.1(g)(3), is described in § 104.20(d).

Proposed § 100.1(g)(4) was intended to be a specific guideline for restoration of nutrients lost during storage or processing. This clarification has been made in the provision now designated as § 104.20(c).

The Nutrient-to-Calorie Balance Concept

5. Although there were objections to the concept of proposed § 100.1(g)(3) concerning the addition of nutrients to foods in proportion to their caloric content, it was evident from the many comments that its application was not fully understood. There were also a number of objections to specific criteria such as the 2,800-kilocalorie base for nutrient requirements.

This principle is established to provide a suitable general basis for fortifying foods for which no specific regulation exists concerning appropriate nutrient levels. A number of regulations already permit or require the addition of nutrients to foods; for example, several standards of identity exist for the enriched forms of certain basic foods including, but not limited to, flour, bread, degerminated corn meal, corn grits, corn meal, and rice. In addition, a nutritional quality guideline has been established for frozen heat-and-serve dinners, and nutritional quality guidelines have been proposed for other classes of foods. Section 101.3(e) (21 CFR 101.3(e), formerly 21 CFR 1.8(e)), provides that foods that substitute for and resemble traditional foods shall not be nutritionally inferior to such foods or shall bear an "imitation" label.

FDA will continue to develop regulations for specific foods and for classes of foods using 21 CFR Part 104, Subpart C—Nutritional Quality Guidelines; 21 CFR Part 102—Common or Usual Name regulations; and food standard regulations under authority of section 401 of the FD&C Act.

In the absence of an applicable regulation governing the enrichment of a food, the nutrient balance concept provides a suitable basis for adding nutrients to fabricated foods that may replace large portions of the total diet. This concept will be particularly useful for foods that are new or unique, and will assure that fortification results in a food of high nutritional quality.

Properly planned meals are composed of selections of foods that complement each other with respect to supplying the essential nutrients in the diet. When the specific use of new or unique products cannot be predicted, it is not possible to anticipate a specific and limited nutrient content or profile. Therefore, when products cannot be categorized as substitutes or replacements for a particular food and a manufacturer elects to add nutrients to such products, the nutrient additions should conform to a profile reflecting all the foods which the product might substitute for or replace in the diet. Because it is impractical to develop such a profile for each food, a logical alternative is a profile that would sustain a balance in the average person's overall nutrient intake by relating nutrient content to caloric content. As stated in the preamble to the 1974 proposal, this approach can also serve as an alternate means for establishing nutritional quality for fabricated foods.

6. There were several objections to the proposed establishment of a 2,800-kilocalorie baseline as a daily standard. Most of those commenting objected on the basis that the 2,800-kilocalorie figure was unrealistically high and not consistent with the reported caloric requirements of a majority of the population. Those commenting urged that a lower figure be adopted, and several comments specifically requested that the calorie standard be lowered to 2,300 kilocalories. Others requested that a 2,000-kilocalorie figure be adopted. A majority of those commenting cited two fundamental reasons for opposing the proposed calorie standard: (1) Setting a caloric standard at an unrealistically high intake would mislead a majority of consumers as to a proper caloric requirement; and (2) Consumers who

normally consume many fewer calories (for example, 1,500 kilocalories per day) would not be receiving adequate amounts of nutrients.

Upon reconsidering the issues, FDA has decided to revise the final policy statement to use a caloric standard of 2,000 kilocalories. The 2,800-kilocalorie value proposed was consistent with the development of the U.S. RDA's in that it approximated the highest mean value listed in the 1968 Recommended Dietary Allowances of the Food and Nutrition Board, National Academy of Sciences/National Research Council (NAS/NRC). There was also concern about unduly high levels of fortification, and by using a higher calorie base this problem would have been reduced. However, after consideration of the comments, FDA has concluded that a 2,800-kilocalorie base is not appropriate for a majority of consumers and may contribute to misunderstanding about the daily caloric requirements of individuals. The 2,000 kilocalorie base is further supported by the recently published food intake analysis from the 1971–1975 Health and Nutrition Examination Survey (DHEW Pub. No. 79–1221), which substantiates the decline in average caloric intakes of Americans.

The 2,000-kilocalorie base, though more realistic, is not intended for use as a uniform daily caloric requirement for individuals. Energy requirements of individuals vary over a wide range, and depend on factors (such as sex, age, state of health, level of physical activity) that differ from one individual to another. The caloric standard is to provide a baseline for fortification in relation to calories, not to provide a recommended caloric requirement for individuals.

A caloric base of 2,000 kilocalories per day will allow nutrients to be added to foods so that each nutrient is present at a level equal to at least 1/20th of the U.S. RDA per 100 kilocalories of food rather than 1/28th of the U.S. RDA per 100 kilocalories of food as originally proposed. The nutrient-to-calorie ratio established is adequate to ensure that most individuals, regardless of their individual calorie requirements, will receive adequate proportions of vitamins and minerals from these foods. It is also adequate to ensure that individuals with caloric intakes above average levels will not be exposed to an excessive intake of any nutrient as a result of consuming foods fortified in this manner.

7. Several comments also objected to the mandatory addition of all 20 nutrients in proposed § 100.1(g)(3)(v), where fortification using a balance of nutrients to calories is described.

Manufacturers expressed concern about the technical difficulties involved in providing all 20 nutrients, especially protein, in precise amounts in a single food. Several of those commenting stated that such inflexibility will curtail development of new, nutritious food products and reduce the number of foods now being fortified with vitamins and minerals. One company suggested that, instead of a single nutrient profile that would require all 20 nutrients, it would be more beneficial to establish a separate nutrient profile for each of several food groups, somewhat analogous to the Basic Four food groups. Another comment suggested that the nutrient balance concept be applicable when four or more nutrients are added in proportion to the caloric contribution of the food.

After reviewing these comments, FDA believes that many of them did not consider the entire range of options encompassed within the proposed regulatory approach. The addition of nutrients to food in proportion to the caloric contribution is only one of several ways in which nutrients might be added to food under these guidelines:

(1) Nutrients may be added to foods in accordance with standards of identity established under section 401 of the FD&C Act. Such standards expressly permit or require the addition of such nutrients.

(2) Dietary supplements may be formulated as provided for in section 411 of the FD&C Act.

(3) Nutrients may be added to foods in order to comply with an applicable nutritional quality guideline established in Part 104, Subpart C.

(4) Nutrients may be added to foods as provided for in an applicable common or usual name regulation established in 21 CFR Part 102.

(5) Nutrients may be added to foods if required to restore nutrients lost in storage and/or processing if all the conditions established by the new § 104.20(c) have been met.

In the absence of a specific regulation, a food that substitutes for and resembles another food must provide nutrients at levels nutritionally equivalent to the food it resembles or bear an "imitation" legend in accordance with 21 CFR 101.3(e) formerly 21 CFR 1.8(e).

In addition to these bases for fortification, nutrients may be added to a food in proportion to its caloric content if the food satisfies all the conditions established by new § 104.20(d).

The addition of nutrients to foods based on proportioning nutrients to caloric content is not appropriate in cases where the nutrient addition or composition for a food or class of foods has already been established by an applicable Federal regulation. In addition, fortification pursuant to this concept may not be appropriate if the food is represented as a substitute for and made to resemble traditional food. Representation plays an important part in determining an appropriate fortification mechanism. For example, a product represented as a "formulated meal replacement" designed to be used in a weight reduction program is more appropriately fortified to replace those vitamins and minerals normally provided by a traditional meal that contains more calories. If it were fortified on the basis of its caloric contribution it would not, in all cases, provide appropriate amounts of necessary vitamins and minerals. The proposed regulation establishing a nutritional quality guideline for formulated meal replacements and formulated meal bases (39 FR 20905; June 14, 1974) would provide more appropriate guidance for formulating such foods.

The comment requesting that several distinct nutrient profiles be established for basic types of foods based on nutrient compatibility and technological ease of adding certain nutrient groups did not provide any data or rational basis for establishing such profiles, other than suggesting a parallel to the Basic Four food groups.

FDA concludes that for the concept of "nutrient balance" to be preserved, all the vitamins, minerals, and protein listed in the original proposal should be present at the levels specified in § 104.20(d), except that the addition of vitamin D, iodine, and protein is optional.

There is a relatively narrow range of safety for vitamin D and a sufficient amount of this nutrient already is in the diet. The Total Diet Study by the FDA indicates that average dietary iodine intakes, though considered safe, are several-fold above the U.S. RDA. Hence there is no nutritional reason for the addition of these nutrients when the nutrient balance mechanism is used, and making these nutrients optional is highly unlikely to lead to, or change significantly, an imbalance of these nutrients in the diet. The optional status of protein is explained in paragraph 8 below.

Because of the many ways provided for food fortification, these fortification principles should not result in a reduction in the number of foods being rationally fortified. FDA is also confident that there is sufficient flexibility in this approach so as not to

hamper the development of new nutritious food products.

8. Several comments objected to the inclusion of protein among the required nutrients in proposed § 100.1(g)(3)(v). One trade association objected to protein being considered an "added nutrient" under the general principles because it is itself a food and not added on the same basis as micro-nutrients. Several comments cited the technical difficulties involved with adding protein on the same basis as other nutrients, and most stated that it would be impossible to add protein to some classes of food because of the amounts of protein required and because protein itself contributes substantially to the caloric value of the food.

FDA has found these comments to be persuasive, and it has made protein optional when nutrients are added to food on the basis of the "nutrient balance" concept. Because protein is a macro-nutrient, like carbohydrate and fat, its addition to a food would not, per se, require the addition of vitamins and minerals. Moreover, for most American consumers, there is no deficit of protein in the diet and therefore little justification for addition of protein. Also, it does not appear reasonable to advise against addition of vitamins and minerals to specific foods merely because they do not contain useful amounts of protein. However, if protein alone is added to a food, or protein content is highlighted in any way so as to state or imply nutritional value, the food would still be required to provide nutrition labeling under 21 CFR 101.9 (formerly 21 CFR 1.17) whether or not other nutrients have been added.

9. Some comments expressed concern that proposed § 100.1(g)(3) dealing with fortification using a "nutrient balance" principle would result in dietary imbalances because the nutrient list is limited. One comment recommended that the nutrient list be open-ended so that other nutrients may be added in the future. Another comment recommended that potassium, manganese and linoleic acid be included in the list of nutrients because they were included in the proposal for a formulated meal replacement nutritional quality guideline and have been added to such foods for years.

The general concern for a complete and balanced diet expressed by those commenting is one of the major underlying reasons for promulgating this policy statement. For this reason the list of nutrients specified in § 104.20(d) of the final policy statement should be considered subject to modification as new nutrition knowledge makes changes advisable. It is reasonable to anticipate that FDA will propose a number of additional U.S. RDA's for minerals, such as selenium, molybdenum, and chromium, taking into consideration the recommendations of the Food and Nutrition Board, NSA/NRC, in their new ninth edition of *Recommended Dietary Allowances* (1979, in press).

The minerals potassium and manganese have been added to the list of nutrients in new § 104.20(d), which describes the "nutrient balance" concept. Even though no U.S. RDA has been established for these minerals, they are both recognized as essential nutrients in the diet of man. The levels for these nutrients are based upon safe and adequate dietary intakes as reported in the ninth edition of *Recommended Dietary Allowances*. Manganese is widely distributed in foods of plant and animal origin, but is often lost in processing these foodstuffs. Food for which fortification in proportion to caloric content is appropriate will often contain highly processed ingredients; therefore, it is appropriate to include manganese in the list of nutrients. Potassium is also widely distributed in foods, and a diet of conventional foods usually provides adequate amounts of this nutrient. However, the potassium content of fabricated foods is uncertain. Because these foods may constitute a major part of a diet, it is desirable that they contribute reasonable amounts of potassium.

Linoleic acid has not been added because of the extreme unlikelihood of any dietary deficit of essential fatty acids. Linoleic acid is associated with fat in essentially the same manner that amino acids are associated with protein. Therefore, it is expected that foods fortified using a "nutrient balance" concept will contain linoleic acid if fat is present, but there is no nutritional justification for suggesting it be added to a wide range of foods. In the case of formulated meal replacements and formulated meal bases, linoleic acid is appropriately required because such foods may be used as the sole item of the diet for extended periods of time; and in such cases there is a need to ensure that essential fatty acid requirements are met. Even in this case, however it is unlikely that the requirement will be difficult to meet in view of the ubiquitous nature of fat in the food supply.

10. A number of comments suggested that protein content, as well as calories, could be used as a basis for nutrient density fortification. One comment stated that nutrient additions should be allowed only on the basis of protein content. Another comment agreed with the proposal to exclude protein as a basis for the addition of nutrients, on the ground that difficulties with such a mechanism would be compounded by uncertainties about protein quality.

In the preamble to the 1974 proposal, it was stated that protein as a basis for the addition of other nutrients was considered as an alternative fortification mechanism but was rejected. The use of such a mechanism would not allow for the fortification of protein-free products that may contribute significantly to the caloric value of the diet, and also could encourage the unnecessary addition of protein to foods.

11. One comment pointed out that proposed § 100.1 (g)(3)(iv) would prohibit a product meeting the June 14, 1974 proposed nutritional quality guideline for formulated meal replacements from being labeled as "calorically balanced." Other comments objected to the use of the term "calorically balanced" to describe fortified foods where the nutrients were added in proportion to calories.

A product meeting the requirements of a nutritional quality guideline may properly bear label claims that indicate that it meets the requirements of the guideline. The proposed nutritional quality guideline for formulated meal replacements is intended for a class of foods that may vary in calories per serving but still carry the same complement of vitamins and minerals appropriate for that class of foods. Related to this latter situation is the problem of calorically reduced or low calorie foods (21 CFR 101.66). For calorically reduced foods it would be deemed appropriate to use the normal caloric value of the food for purposes of applying the nutrient/calorie mechanism of enrichment/fortification. The term "calorically balanced" may be confusing and possibly misleading in describing this particular fortification mechanism, and the agency considers the use of "vitamins and minerals (and 'protein' when appropriate) added in proportion to calorie content" more appropriate than "calorically balanced." The policy statement has been revised accordingly.

12. A number of comments objected to the "calorie balance" concept on the basis that it is too rigid in its requirements and that any nutrient or combination of nutrients should be permitted to be added to a food if such nutrient(s) is added in proportion to the caloric content. One comment argued that the addition of vitamin A, thiamine, riboflavin and niacin to potato chips in proportion to calories is rational food fortification. The comment stated that these specific vitamins were selected on

the basis of dietary shortages in children as well as on the assumption that teenagers are not getting adequate thiamine, riboflavin and niacin from enriched grain products.

FDA does not agree that a variety of different combinations of several nutrients added to a food is advisable as a general approach to fortification, even though these nutrients are added in proportion to caloric content, because such a policy does not ensure or promote a balance of all nutrients in the general diet. Accordingly, FDA is continuing to recommend that the full complement of nutrients be added when the addition is being made to balance nutrients with the caloric contribution of the food.

The type of fortification of potato chips suggested by the comment more closely resembles the addition of nutrients as a public health measure to correct for a specific nutrient deficiency. As discussed earlier, any application of this principle must follow the identification of a condition of dietary insufficiency in a segment of the population or evidence that nutrient deficiencies are likely to occur, and the designation of a suitable food or foods that will be consumed by the "target" population to act as vehicles for the added nutrients. Also as discussed, manufacturers should be able to document their findings in this regard to avoid possible sanctions based on a finding that their claims are false or misleading or otherwise in violation of the Federal Food, Drug, and Cosmetic Act.

13. A few comments suggested that to be more flexible the regulation should permit nutrients to be added to foods at a higher density than that permitted by the proposed "nutrient balance" concept. As proposed, nutrients could be added to foods at levels equivalent to 1/28th of the U.S. RDA for each nutrient per 100 kilocalories of food. Those commenting suggested that higher nutrient densities should be allowed for technically feasible formulations, but were opposed to the requirement that all 20 vitamins and minerals listed be added because such formulations are not technically feasible.

Except for the modest increase inherent in changing to the 2,000 kilocalorie base, FDA advises that the higher nutrient density formulations referred to by those commenting may be more accurately described as special dietary foods and labeled accordingly.

The rationale for requiring the addition of all the vitamins and minerals under the "nutrient balance" concept has been discussed in the preceding paragraphs on caloric balance. It is pointed out, again, that this mechanism for food fortification is not appropriate for foods to which regulations with more specific fortification profiles are applicable.

14. Several comments objected to the proposed 56-kilocalorie-per-serving figure as a minimum criterion for foods to which nutrients can be added on the basis of caloric content. Part of the comment's arguments related to justifying the enrichment/fortification of foods below the caloric limit on the basis of their multiple consumption during the day.

FDA has changed the 56-kilocalorie-per-serving minimum to a 40-kilocalorie-per-serving minimum because the other changes in the guidelines, taken together, automatically lead to a 40-kilocalorie-per-serving minimum. Using the base of 2,000 kilocalories, nutrients may be added to foods at levels equivalent to 1/20 or 5 percent of the U.S. RDA for each 100 kilocalories of food. Because nutrients should not be added in amounts less than 2 percent of the U.S. RDA, nutrients should not be added to a product supplying less than 40 kilocalories per serving because of the 2,000-kilocalorie-per-day base. An addition of nutrients in amounts of less than 2 percent does not constitute a nutritionally useful addition of nutrients and could misleadingly suggest the addition is important when it is not.

FDA recognizes that if a substantial number of food items, each contributing a small number of calories, is consumed on a regular daily basis, these foods may become nutritionally significant for some consumers. However, it is not appropriate to fortify foods based on multiple consumption. Eating habits are so varied that it would be almost impossible to establish norms for these foods so that their caloric contribution to the daily diet could be gauged.

Therefore, FDA is retaining a 40-kilocalorie-per-serving minimum with no provision for multiple consumption of food servings that fall below the 40-kilocalorie-per-serving minimum.

Restoration

15. Most comments supported the part of the proposal permitting nutrients lost in processing to be restored to foods. Several comments, however, questioned specific aspects of this fortification mechanism. Several comments suggested that the definition of "restoration" in proposed § 100.1(g)(4) be expanded to include losses prior to processing, and that the standard of reference for restoration should be the nutrient content of the food or food ingredients at the time of harvest.

Losses of some nutrients may occur under normal storage and handling conditions, in addition to those that may occur during processing; hence, it is reasonable that restoration of nutrients include all losses of nutrients that occur after harvesting. The principle has been revised to allow restoration, where applicable, to include nutrient losses incurred during storage and handling of the freshly harvested food or ingredients of a food.

16. Several comments asked for interpretation of proposed § 100.1(g)(4). They pointed out that the proposed regulation permitted restoration generally, but that proposed § 100.1(g)(4)(iii) appeared to prohibit restoration without a negative label statement as required by 21 CFR 104.5(f) if there is a nutritional quality guideline for the food that calls for higher nutrient levels. Other comments also asked whether restoration would be permitted for conventional foods such as cereals if there were nutritional quality guidelines for their fortified counterparts (for example, fortified ready-to-eat cereal).

FDA advises that when a regulation prohibits, permits, or requires the addition of nutrients to a food or class of foods the nutrient levels specified in that regulation generally take into account concepts of enrichment/fortification and restoration. Therefore, the policy statement specifically states that restoration as a mechanism for food fortification is appropriate only in the absence of an applicable Federal regulation that specifically prohibits, permits, or requires the addition of nutrients to the food in question. However, FDA believes it should be permissible to restore nutrients to foods in the circumstances raised in the comments, that is, in the case of a food that may be, but has not been, voluntarily fortified in accordance with a Federal regulation. Federal regulations such as nutritional quality guidelines provide for fortification on a voluntary basis in a nutritionally appropriate way. Nutrients may be restored to these foods in accordance with the general principles in this document only when the food could have, but has not, in fact, been fortified in accordance with another Federal regulation that voluntarily permits fortification. A clarification of this point has been included in § 104.20(c)(4).

17. One comment requested that the criteria and specifics of restoration be further defined so that manufacturers would know whether it is required that all nutrients reduced in processing be restored or whether a particular nutrient could be selected for restoration. Other

comments requested additional information as to the specific levels of the nutrient additions. One comment requested that restoration be permitted at levels equivalent to 1.5 times the preprocessed levels to take into account and guard against any additional losses that may occur from storage and handling after leaving the manufacturing plant.

FDA has concluded that all nutrients, including protein, iodine and vitamin D, lost in measurable amounts (that is, at least 2 percent of the U.S. RDA per serving) during processing, storage, and handling should be restored if the restoration mechanism is used. This change has been made because of concern that partial restoration may result in restoration of only those nutrients that are least expensive, or technologically easiest to add, or only those required to be listed in nutrition labeling. Without this amendment, restoration practices could contribute to nutrient imbalance in the food supply.

The restoration principle permits the addition of vitamins, minerals, and proteins to a food to restore such nutrients to levels representative of the food before storage, handling, and processing if: (1) The nutrient(s) is shown by adequate scientific documentation to have been lost in a measurable amount equal to at least 2 percent of the U.S. RDA in a normal serving of the food; (2) Good manufacturing practices and normal storage and handling procedures cannot prevent the loss of such nutrients; (3) The food is not the subject of any other Federal regulation for a food or class of foods that requires or prohibits nutrient addition(s), or the food has not been fortified in accordance with any other Federal regulation that permits voluntary nutrient addition(s); (4) All nutrients that are lost in measurable amounts are restored; (5) All ingredients of the food product that contribute nutrients are considered in determining restoration levels; and (6) Nutrients are restored to levels representative of such food before storage, handling, and processing within good manufacturing limits.

Blanket restoration of all nutrients to 1.5 times preprocessing levels in consideration of future losses that may occur during storage and handling is considered by FDA to be inappropriate. One proviso for restoration is that normal storage and handling procedures cannot prevent the loss of a nutrient(s). Under normal conditions, such losses should be minimal for minerals and the more stable vitamins such as niacin. For the less stable vitamins, such as vitamin C, addition of reasonable amounts in excess of the restoration and declared level is acceptable to account for possible losses during normal storage and handling but not the extent of blanket overages for all nutrients. Except as discussed above, any addition in excess of actual restorative levels would not be considered restoration.

Labeling Statements, Claims, and Definitions

The 1974 proposal contained several provisions dealing with permitted or required label statements. In summary, the proposal would have extended the use of the affirmative statement, previously permitted only for those foods that comply with all the requirements of a nutritional quality guideline under 21 CFR 104.1(b) (formerly 21 CFR 100.1(b)), to foods meeting the requirements of an applicable food standard promulgated under section 401 of the act that "prescribes the nutrient additions to a food." The affirmative statement permitted reads: "This product provides nutrients in amounts appropriate for this class of foods as determined by the U.S. Government." The proposal only considered expanding use of the statement already permitted under 21 CFR 104.1(b). Thus comments objecting to the use of this statement for products meeting the requirement of a nutritional quality guideline or urging that the statement itself be modified for these foods are not relevant to the proposal. The proposal to expand the use of the statement is being withdrawn for the reasons discussed below.

18. A few comments objected to the positive label statement permitted by proposed § 100.1(b) on the ground that such a statement would be viewed by consumers as a Federal "stamp of approval" for certain products, and that such an assumption might mislead consumers into believing that such products are superior to traditional foods, without added vitamins, such as those the consumer prepares from raw ingredients. Another comment objected to such affirmative labeling statements because a majority of foods, unable to use such a statement, do in fact provide nutrients in appropriate amounts. Still other comments urged that additional classes of foods be allowed to use such a statement, when factual, and that expanded use of the statement be extended to raw agricultural commodities, foods restored to preprocessing levels, and foods with nutrients added in proportion to calories, in addition to extending its use to standardized foods when nutrient additions have been prescribed by the standard.

Some of the comments objecting to these provisions of the proposal were similar to those received in response to the initial proposal of general principles for the establishment of nutritional quality guidelines, published in the Federal Register of December 23, 1971 (36 FR 24822) and were discussed in the preamble to the nutritional quality guideline regulations published in the Federal Register of March 14, 1973 (38 FR 6969).

FDA concluded at that time, on the basis of consumers' expressed desires to be informed of which foods meet guideline requirements, that the affirmative statement would be permitted. To minimize the possibility of unwarranted or misleading use of such a statement, the scope of the statement was narrowed and a type size limit was imposed on the use of the statement.

All these comments have been considered carefully, and FDA has concluded that a comprehensive substantive rule governing the labeling of fortified foods is not feasible at this time because there are simply too many potential food labeling issues involved. These issues are both diverse and complex, and solutions to some of the problems concerning the labeling of fortified foods cannot be provided in this document. Therefore, a course of action has been chosen that will provide manufacturers with guidance on nutrient additions if they elect to fortify foods with proteins, vitamins and/or minerals.

Most labeling issues involving fortified foods can more realistically be dealt with individually, as specific problems become more clearly identified. Therefore, the expansion of the use of the affirmative statement will not be considered until more experience is gained concerning its effectiveness with nutritional quality guidelines.

19. One comment requested clarification of the affirmative labeling statement. It asked when "natural foods" that meet an applicable nutritional quality guideline are eligible to carry the affirmative statement.

It is assumed that the term "natural food" as used in this comment refers to food without added nutrients. FDA advises that any food that complies with an applicable nutritional quality guideline is eligible to bear the guideline statement regardless of whether such food naturally contains the appropriate nutrients or the nutrients were added separately. There is no difference in nutritional quality between two foods simply because nutrients are added as discrete substances in the one case and are naturally present in the other. One

of the reasons a positive statement is useful is that it informs consumers in a positive manner that a food meets an appropriate nutritional profile for that particular food.

20. The proposal also would have extended the use of the negative statement previously required under 21 CFR 100.1(f) for products within a class of foods for which a nutritional quality guideline has been established and to which a discrete nutrient or nutrients have been added but which fail to comply with the provisions of the guideline. The proposal would have extended the requirement for the negative labeling statement to any food to which discrete nutrients have been added but which fails to comply with any of the various fortification mechanisms established by the "general principles" regulation.

A number of comments opposed this requirement of a disclaimer statement for any food on the ground that such a provision is beyond FDA's statutory authority. Others argued that the extension of the disclaimer statement to other foods fortified with vitamins and minerals is actually assumption of "preclearance authority" for food formulation, which is not granted to FDA by any statute.

In the preamble to the proposal it was emphasized that the regulation was not intended to encourage the food industry to put vitamins, minerals, or protein into every food. Certainly not every food is an appropriate carrier for additional nutrients. Indiscriminate fortification of foods could lead to confusion about the necessity or propriety of food fortification. It could mislead consumers about the overall nutritional value of various kinds of foods and could lead to potentially serious health problems.

FDA does agree, however, that an across-the-board requirement to provide a disclaimer statement is not justified. It would impose considerable restrictions on manufacturers and would create a large administrative burden as well because manufacturers probably would file many petitions to amend the regulations. FDA has concluded that specific problems with regard to labeling of fortified foods are more appropriately addressed apart from this document.

Other labeling provisions in the proposal were not adopted in this document because this document provides guidelines for nutrient additions rather than labeling regulations. One proposed provision would have permitted certain labeling claims when particular fortification mechanisms are employed. Specific label statements were also proposed for food fortified under restoration, enrichment/fortification, or caloric balance principles. Another proposal would have proscribed certain labeling claims such as those in proposed § 100.1(i)(1), which reads: "No claim or statement may be made on the label or in labeling that any vitamin, mineral, or protein has been added to a food, either in general terms, e.g., "fortified", or in specific terms, e.g., "added", if it is added pursuant to § 1.8(e) of this chapter (now § 101.3(e)) except that a nutrient addition shall be declared by common or usual name in the ingredient statement." Proposed § 100.1(i) (2) and (3) contained similar provisions for labeling claims.

21. Several comments supported the definitions for "enrichment," "fortification," and "restoration" in § 100.1(j) of the proposal. Some comments, however, expressed doubt that consumers would be likely to distinguish between "enriched" and "fortified" and urged a more general definition.

FDA advises that, since these definitions were proposed in June of 1974, the U.S. Department of Agriculture has published the results of a survey "Homemakers, Food and Nutrition Knowledge, Practices, and Opinions," Home Economics Research Report No. 39. This survey found that many people apparently view "enriched" as being synonymous with "fortified," and that both are viewed as meaning simply the addition of nutrients. Therefore, FDA concludes that for label and labeling purposes it will be less confusing to consumers if no distinction is made between these terms. The statement of policy, therefore, permits the term "enriched," "fortified," or similar terms to be used interchangeably, unless an applicable Federal regulation requires more specific words or statements.

The definition of "restoration" has also been amended to include the nutrient loss from harvesting to processing and is discussed in paragraph 15 above.

22. Several comments objected to the prohibition of labeling claims for foods to which nutrients are added to make them nutritionally equivalent to the foods they resemble and for which they substitute. The objections declared that the proposed prohibition was an unnecessary restriction on making truthful and nonmisleading statements.

FDA rejects that argument. The preamble to the proposed regulation explained that the labeling claims would be prohibited on such foods to protect consumers from being misled into thinking that processed foods with nutrients added to make them nutritionally equivalent to foods they resemble and substitute for are nutritionally superior to these foods. A special labeling announcement declaring that nutrients have been added is inappropriate because they had to be added to achieve the nutritional comparability and avoid the imitation label. The revised policy statement continues to state FDA's position that it is inappropriate to make claims about the addition of nutrients to a food that has been fortified to make it nutritionally equivalent to the food it replaces. Further, FDA points out that consumers can learn of the added nutrients, which must be included by common or usual name in the ingredient list.

23. A few comments requested clarification of proposed § 100.1(d) and (i)(2) concerning prohibitions of certain label claims. Those commenting stated that the two paragraphs apparently conflicted in that § 100.1(i)(2) permits comparative statements and § 100.1(d) prohibits comparative statements. Other comments simply expressed confusion as to the exact meaning of proposed § 100.1(d).

FDA agrees that these provisions were not clear. They were intended to prevent a labeling distinction being made between products to which nutrients had been added and those that did not require such additions to meet the requirements of applicable nutritional quality guidelines. The nutritional quality guidelines regulations already contain a provision (21 CFR 104.5(d)) essentially the same as proposed § 100.1(d). Any distinction between natural and synthetic vitamins will continue to be prohibited under § 101.9(i)(6), and claims for nutritional superiority will be controlled by § 101.9(c)(7)(v). Therefore, these restrictions have not been included in this statement of policy.

Miscellaneous Comments

24. One comment suggested that the "general principles" apply to the addition of amino acids to improve the protein quality of foods.

FDA advises that amino acids, when added to a food to improve its protein quality, are considered food additives and are regulated under 21 CFR 172.320 *Amino acids* (formerly 21 CFR 121.1002). There is no need for repetition of the requirements of § 172.320.

25. One comment from industry requested clarification as to whether the proposal applies only to human food or whether it includes animal food.

The proposed "general principles" regulations apply only to food for human consumption and not to animal food. The recodification in the **Federal**

Register of March 15, 1977 (42 FR 14302) assigns these regulations to 21 CFR Chapter I, Subchapter B—Food for Human Consumption.

This final order was proposed prior to Executive Orders 11821 and 12044, requiring agencies in the executive branch to review regulatory and legislative proposals they initiate for economic impact, and so does not require economic impact review.

Therefore, in accordance with the foregoing discussion, and under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403(a), 701(a), 52 Stat. 1041 and 1047 as amended, 1055 (21 U.S.C. 321(n), 343(a), 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 104 is amended by adding new Subpart B consisting at this time of § 104.20, to read as follows:

PART 104—NUTRITIONAL QUALITY OF FOODS

Subpart B—Fortification Policy

§ 104.20 Statement of purpose.

(a) The fundamental objective of this subpart is to establish a uniform set of principles that will serve as a model for the rational addition of nutrients to foods. The achievement and maintenance of a desirable level of nutritional quality in the nation's food supply is an important public health objective. The addition of nutrients to specific foods can be an effective way of maintaining and improving the overall nutritional quality of the food supply. However, random fortification of foods could result in over- or underfortification in consumer diets and create nutrient imbalances in the food supply. It could also result in deceptive or misleading claims for certain foods. The Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. To preserve a balance of nutrients in the diet, manufacturers who elect to fortify foods are urged to utilize these principles when adding nutrients to food. It is reasonable to anticipate that the U.S. RDA's as delineated in § 101.9 of this chapter and in paragraph (d) of this section will be amended from time to time to list additional nutrients and/or to change the levels of specific U.S. RDA's as improved knowledge about human nutrient requirements and allowances develops. The policy set forth in this section is based on U.S. dietary practices and nutritional needs and may not be applicable in other countries.

(b) A nutrient(s) listed in paragraph (d)(3) of this section may appropriately be added to a food to correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency disease if:

(1) Sufficient information is available to identify the nutritional problem and the affected population groups, and the food is suitable to act as a vehicle for the added nutrients. Manufacturers contemplating using this principle are urged to contact the Food and Drug Administration before implementing a fortification plan based on this principle.

(2) The food is not the subject of any other Federal regulation for a food or class of food that requires, permits, or prohibits nutrient additions. (Other Federal regulations include, but are not limited to, standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, nutritional quality guidelines established in Subpart C of this part, and common or usual name regulations established in Part 102 of this chapter.)

(c) A nutrient(s) listed in paragraph (d)(3) of this section may appropriately be added to a food to restore such nutrient(s) to a level(s) representative of the food prior to storage, handling, and processing, when:

(1) The nutrient(s) is shown by adequate scientific documentation to have been lost in storage, handling, or processing in a measurable amount equal to at least 2 percent of the U.S. RDA (and 2 percent of 2.5 grams of potassium and 4.0 milligrams of manganese, when appropriate) in a normal serving of the food;

(2) Good manufacturing practices and normal storage and handling procedures cannot prevent the loss of such nutrient(s),

(3) All nutrients, including protein, iodine and vitamin D, that are lost in a measurable amount are restored and all ingredients of the food product that contribute nutrients are considered in determining restoration levels; and

(4) The food is not the subject of any other Federal regulation that requires or prohibits nutrient addition(s), or the food has not been fortified in accordance with any other Federal regulation that permits voluntary nutrient additions.

(d) A nutrient(s) listed in paragraph (d)(3) of this section may be added to a food in proportion to the total caloric content of the food, to balance the vitamin, mineral, and protein content if:

(1) A normal serving of the food contains at least 40 kilocalories (that is, 2 percent of a daily intake of 2,000 kilocalories);

(2) The food is not the subject of any other Federal regulation for a food or class of food that requires, permits, or prohibits nutrient additions; and

(3) The food contains all of the following nutrients per 100 kilocalories based on a 2,000-kilocalorie total intake as a daily standard:

Nutrient and unit of measurement	U.S. RDA [1]	Amount per 100 kilocalories
Protein (optional), gram (g)	[2] 65	3.25
	45	2.25
Vitamin A, international unit (UI)	5000	250
Vitamin C, milligram (mg)	60	3
Thiamine, milligram (mg)	1.5	0.075
Riboflavin, milligram (mg)	1.7	0.085
Niacin, milligram (mg)	20	1.0
Calcium, gram (g)	1	0.05
Iron, milligram (mg)	18	0.9
Vitamin D (optional), international unit (IU)	400	20
Vitamin E, international unit (IU)	30	1.5
Vitamin B-6, milligram (mg)	2	0.1
Folic acid, milligram (mg)	0.4	0.02
Vitamin B-12, microgram (mcg)	6	0.3
Phosphorus, gram (g)	1	0.05
Iodine (optional), microgram (mcg)	150	7.5
Magnesium, milligram (mg)	400	20
Zinc, milligram (mg)	15	0.75
Copper, milligram (mg)	2	0.1
Biotin, milligram (mg)	0.3	0.015
Pantothenic acid, milligram (mg)	10	0.5
Potassium, gram (g)	[3]	0.125
Manganese, milligram (mg)	[3]	0.2

[1] U.S. Recommended Daily Allowance (U.S. RDA) for adults and children 4 or more years of age.

[2] If the protein efficiency ratio of protein is equal to or better than that of casein, the U.S. RDA is 45 g.

[3] No U.S. RDA has been established for either potassium or manganese; daily dietary intakes of 2.5 g. and 4.0 mg., respectively, are based on the 1979 Recommended Dietary Allowances of the Food and Nutrition Board, National Academy of Sciences-National Research Council.

(e) A nutrient(s) may appropriately be added to a food that replaces traditional food in the diet to avoid nutritional inferiority in accordance with § 101.3(e)(2) of this chapter.

(f) Nutrient(s) may be added to foods as permitted or required by applicable regulations established elsewhere in this chapter.

(g) A nutrient added to a food is appropriate only when the nutrient:

(1) Is stable in the food under customary conditions of storage, distribution, and use;

(2) Is physiologically available from the food;

(3) Is present at a level at which there is a reasonable assurance that consumption of the food containing the added nutrient will not result in an excessive intake of the nutrient, considering cumulative amounts from other sources in the diet; and

(4) Is suitable for its intended purpose and is in compliance with applicable provisions of the act and regulations governing the safety of substances in food.

(h) Any claims or statements in the labeling of food about the addition of a

vitamin, mineral, or protein to a food shall be made only if the claim or statement is not false or misleading and otherwise complies with the act and any applicable regulations. The following label claims are acceptable:

(1) The labeling claim "fully restored with vitamins and minerals" or "fully restored with vitamins and minerals to the level of unprocessed ——" (the blank to be filled in with the common or usual name of the food) may be used to describe foods fortified in accordance with the principles established in paragraph (c) of the section.

(2) The labeling claim, "vitamins and minerals (and "protein" when appropriate) added are in proportion to caloric content" may be used to describe food fortified in accordance with the principles established in paragraph (d) of this section.

(3) When labeling claims are permitted, the term "enriched," "fortified," "added," or similar terms may be used interchangeably to indicate the addition of one or more vitamins or minerals or protein to a food, unless an applicable Federal regulation requires the use of specific words or statements.

(i) It is inappropriate to make any claim or statement on a label or in labeling, other than in a listing of the nutrient ingredients as part of the ingredient statement, that any vitamin, mineral, or protein has been added to a food to which nutrients have been added pursuant to paragraph (e) of this section.

Effective date. This policy statement is effective February 25, 1980.

(Secs. 201(n), 403(a), 701(a), 52 Stat. 1041 and 1047 as amended, 1055 (21 U.S.C. 321(n), 343(a), 371(a)).)

Dated: January 18, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80-2380 Filed 1-24-80; 8:45 am]

BILLING CODE 4110-03-M